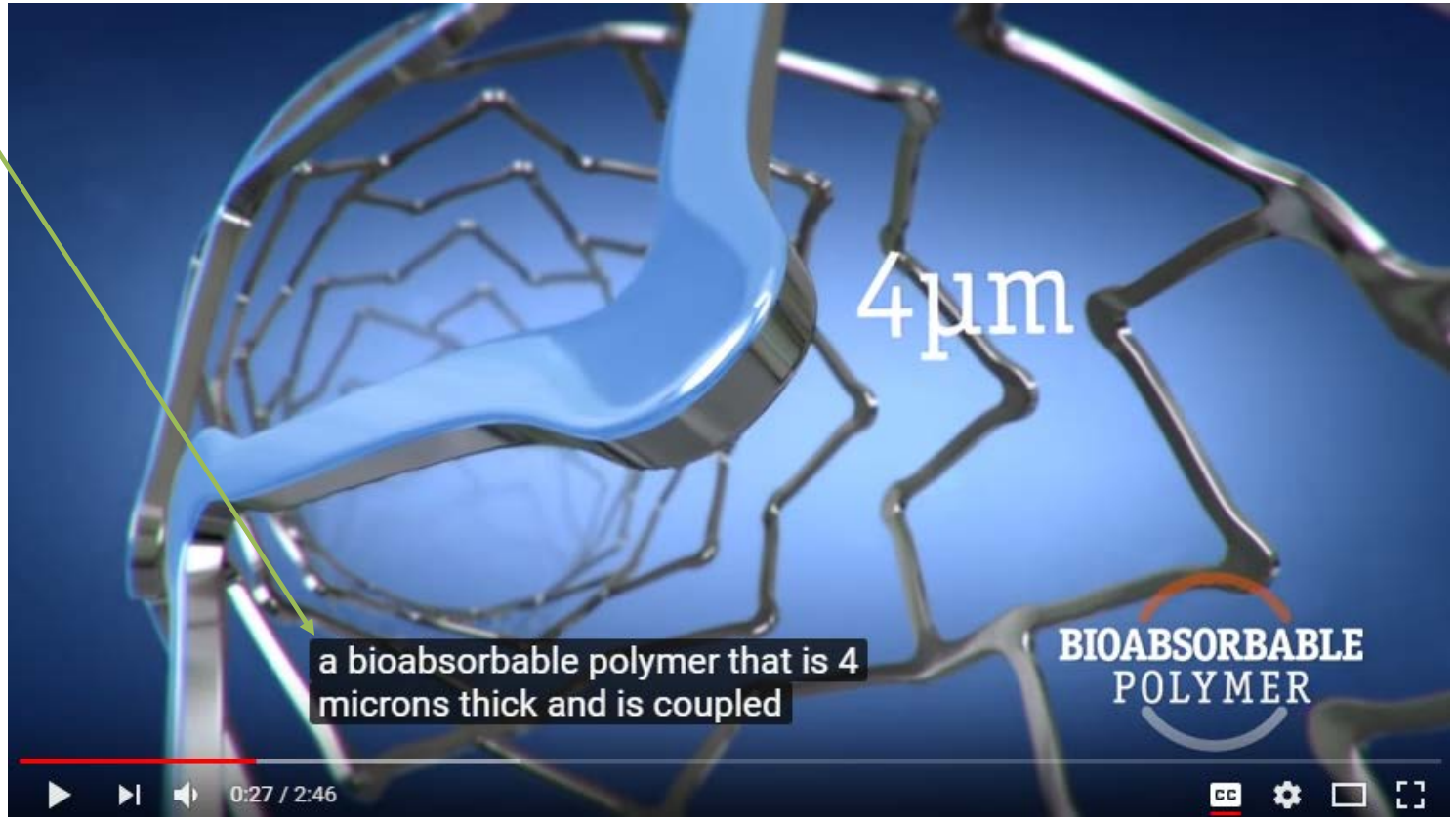
EXHIBIT B

USP6390296 Boston Scientific Synergy Everolimus-Eluting Pt-Cr Coronary Stent

Claim 1

A composition comprising at least one **(A) biodegradable polymer fiber**

(A)



Sources: http://www.bostonscientific.com/en-US/products/stents--coronary/bioabsorbable-polymer-stent.html

USP6390296 Boston Scientific Synergy Everolimus-Eluting Pt-Cr Coronary Stent

Claim 1

A composition comprising at least one **(A) biodegradable polymer fiber**

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System labeling.

V. DEVICE DESCRIPTION

The SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY) is a device/drug combination product that provides a mechanical structure for vascular lumen support (primary mode of action) and a pharmacological agent (everolimus) targeted towards reducing the injury response. The System consists of a drug/polymer-coated balloon-expandable stent, pre-mounted on a Monorail™ (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The drug/polymer coating consists of a bioabsorbable polymer, poly (D,L-lactide-co-glycolide) (PLGA), and the active pharmaceutical ingredient, everolimus. The characteristics of the SYNERGY stent system are described in **Table V-T1**.

Table V-T1: SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System Product Description

	SYNERGY Monorail Stent Delivery System	SYNERGY Over-the-Wire Stent Delivery System
Available Stent Lengths (mm)	8, 12, 16, 20, 24, 28, 32, 38	
Available Stent Diameters (mm)	2.25, 2.50, 2.75, 3.00, 3.50, 4.00	
Stent Material	Platinum Chromium Alloy (PtCr)	
Stent Strut Thickness	0.074 mm for diameters 2.25 mm to 2.75 mm 0.079 mm for diameters 3.00mm to 3.50 mm 0.081 mm for diameter of 4.00 mm	
Drug Product	An abluminal (outer surface of the stent) coating of a polymer carrier with approximately 1 µg of everolimus per mm² of total stent surface area with a maximum nominal drug content of 287.2 µg on the largest stent (4.00 x 38 mm).	
Delivery System		
Effective Length	144 cm	
Delivery System Y-Adapter Ports	Single access port to inflation lumen. Guidewire exit port is located approximately 25 cm from tip. Designed for guidewire ≤0.014 inches (0.36 mm)	Y-Connector (Side arm for access to balloon inflation/deflation lumen. Straight arm is continuous with shaft inner lumen). Designed for guidewire ≤0.014 inches (0.36 mm)
Stent Delivery	A balloon, with two radiopaque balloon markers, nominally placed 0.4 mm (0.016 inches) beyond the stent at each end.	
Balloon Inflation Pressure	Nominal Inflation Pressure: • Diameters 2.25 mm, 2.50 mm, 2.75 mm, 3.00 mm, 3.50 mm, 4.00 mm: 11 atm (1117 kPa)	
	Rated Burst Inflation Pressure: • Diameters 2.25 mm – 2.75 mm: 18 atm (1827 kPa) • Diameters 3.00 mm – 4.00 mm: 16 atm (1620 kPa)	

PMA P150003: FDA Summary of Safety and Effectiveness Data Page 2

DEVICE DESCRIPTION

The SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY) is a device/drug combination product that provides a mechanical structure for vascular lumen support (primary mode of action) and a pharmacological agent (everolimus) targeted towards reducing the injury response. The System consists of a drug/polymer-coated balloon-expandable stent, pre-mounted on a Monorail™ (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The drug/polymer coating consists of a bioabsorbable polymer, poly (D,L-lactide-co-glycolide) (PLGA), and the active pharmaceutical ingredient, everolimus. The characteristics of the SYNERGY stent system are described in **Table V-T1**.

Sources: FDA P150003 PMA, 2015

USP6390296 Boston Scientific Synergy Everolimus-Eluting Pt-Cr Coronary Stent

Claim 1

A composition comprising at least one **(A) biodegradable polymer fiber**

Poly (lactic-co-glycolic acid) (PLGA) copolymers have been broadly used in controlled drug release applications. Because these polymers are biodegradable, they provide an attractive option for drug delivery vehicles. There are a variety of material, processing, and physiological factors that impact the degradation rates of PLGA polymers and concurrent drug release kinetics. This work is intended to provide a comprehensive and collective review of the physicochemical and physiological factors that dictate the degradation behavior of PLGA polymers and drug release from contemporary PLGA-based drug-polymer products. In conjunction with the existing experimental results, analytical and numerical theories developed to predict drug release from PLGA-based polymers are summarized and correlated with the experimental observations.

Sources: Polymer degradation and drug delivery in PLGA-based drug-polymer applications: a review of experiments and theories, PubMed ID: #27098357, 2016

USP6390296 Boston Scientific Synergy Everolimus-Eluting Pt-Cr Coronary Stent

Claim 1

wherein said fiber is composed of a **(B) first phase** and a **(C) second phase**,

IV. **WARNINGS AND PRECAUTIONS**

The warnings and precautions can be found in the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System labeling.

V. **DEVICE DESCRIPTION**

The SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY) is a device/drug combination product that provides a mechanical structure for vascular lumen support (primary mode of action) and a pharmacological agent (everolimus) targeted towards reducing the injury response. The System consists of a drug/polymer-coated balloon-expandable stent, pre-mounted on a Monorail™ (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The drug/polymer coating consists of a bioabsorbable polymer, poly (D,L-lactide-co-glycolide) (PLGA), and the active pharmaceutical ingredient, everolimus. The characteristics of the SYNERGY stent system are described in **Table V-T1**.

Table V-T1: SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System Product Description

	SYNERGY Monorail Stent Delivery System	SYNERGY Over-the-Wire Stent Delivery System
Available Stent Lengths (mm)	8, 12, 16, 20, 24, 28, 32, 38	
Available Stent Diameters (mm)	2.25, 2.50, 2.75, 3.00, 3.50, 4.00	
Stent Material	Platinum Chromium Alloy (PtCr)	
Stent Strut Thickness	0.074 mm for diameters 2.25 mm to 2.75 mm 0.079 mm for diameters 3.00mm to 3.50 mm 0.081 mm for diameter of 4.00 mm	
Drug Product	An abluminal (outer surface of the stent) coating of a polymer carrier with approximately 1 µg of everolimus per mm² of total stent surface area with a maximum nominal drug content of 287.2 µg on the largest stent (4.00 x 38 mm).	
Delivery System		
Effective Length	144 cm	
Delivery System Y-Adapter Ports	Single access port to inflation lumen. Guidewire exit port is located approximately 25 cm from tip. Designed for guidewire ≤0.014 inches (0.36 mm)	Y-Connector (Side arm for access to balloon inflation/deflation lumen. Straight arm is continuous with shaft inner lumen). Designed for guidewire ≤0.014 inches (0.36 mm)
Stent Delivery	A balloon, with two radiopaque balloon markers, nominally placed 0.4 mm (0.016 inches) beyond the stent at each end.	
Balloon Inflation Pressure	Nominal Inflation Pressure: • Diameters 2.25 mm, 2.50 mm, 2.75 mm, 3.00 mm, 3.50 mm, 4.00 mm: 11 atm (1117 kPa)	
	Rated Burst Inflation Pressure: • Diameters 2.25 mm – 2.75 mm: 18 atm (1827 kPa) • Diameters 3.00 mm – 4.00 mm: 16 atm (1620 kPa)	

PMA P150003: FDA Summary of Safety and Effectiveness Data Page 2

DEVICE DESCRIPTION

The SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY) is a device/drug combination product that provides a mechanical structure for vascular lumen support (primary mode of action) and a pharmacological agent (everolimus) targeted towards reducing the injury response. The System consists of a drug/polymer-coated balloon-expandable stent, pre-mounted on a Monorail™ (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The drug/polymer coating consists of a bioabsorbable polymer, poly (D,L-lactide-co-glycolide) (PLGA), and the active pharmaceutical ingredient, everolimus. The characteristics of the SYNERGY stent system are described in **Table V-T1**.

(B)

(C)

Sources: FDA P150003 PMA, 2015

Claim 1

the **first** and **second phases** (D) being immiscible,

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System labeling.

V. DEVICE DESCRIPTION

The SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY) is a device/drug combination product that provides a mechanical structure for vascular lumen support (primary mode of action) and a pharmacological agent (everolimus) targeted towards reducing the injury response. The System consists of a drug/polymer-coated balloon-expandable stent, pre-mounted on a Monorail™ (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The drug/polymer coating consists of a bioabsorbable polymer, poly (D,L-lactide-co-glycolide) (PLGA), and the active pharmaceutical ingredient, everolimus. The characteristics of the SYNERGY stent system are described in **Table V-T1**.

Table V-T1: SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System Product Description

	SYNERGY Monorail Stent Delivery System	SYNERGY Over-the-Wire Stent Delivery System
Available Stent Lengths (mm)	8, 12, 16, 20, 24, 28, 32, 38	
Available Stent Diameters (mm)	2.25, 2.50, 2.75, 3.00, 3.50, 4.00	
Stent Material	Platinum Chromium Alloy (PtCr)	
Stent Strut Thickness	0.074 mm for diameters 2.25 mm to 2.75 mm 0.079 mm for diameters 3.00mm to 3.50 mm 0.081 mm for diameter of 4.00 mm	
Drug Product	An abluminal (outer surface of the stent) coating of a polymer carrier with approximately 1 µg of everolimus per mm^2 of total stent surface area with a maximum nominal drug content of 287.2 µg on the largest stent (4.00 x 38 mm).	
Delivery System		
Effective Length	144 cm	
Delivery System Y-Adapter Ports	Single access port to inflation lumen. Guidewire exit port is located approximately 25 cm from tip. Designed for guidewire ≤0.014 inches (0.36 mm)	Y-Connector (Side arm for access to balloon inflation/deflation lumen. Straight arm is continuous with shaft inner lumen). Designed for guidewire ≤0.014 inches (0.36 mm)
Stent Delivery	A balloon, with two radiopaque balloon markers, nominally placed 0.4 mm (0.016 inches) beyond the stent at each end.	
Balloon Inflation Pressure	Nominal Inflation Pressure: • Diameters 2.25 mm, 2.50 mm, 2.75 mm, 3.00 mm, 3.50 mm, 4.00 mm: 11 atm (1117 kPa)	
	Rated Burst Inflation Pressure: • Diameters 2.25 mm – 2.75 mm: 18 atm (1827 kPa) • Diameters 3.00 mm – 4.00 mm: 16 atm (1620 kPa)	

PMA P150003: FDA Summary of Safety and Effectiveness Data Page 2

DEVICE DESCRIPTION

The SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY) is a device/drug combination product that provides a mechanical structure for vascular lumen support (primary mode of action) and a pharmacological agent (everolimus) targeted towards reducing the injury response. The System consists of a drug/polymer-coated balloon-expandable stent, pre-mounted on a Monorail™ (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The drug/polymer coating consists of a bioabsorbable polymer, poly (D,L-lactide-co-glycolide) (PLGA), and the active pharmaceutical ingredient, everolimus. The characteristics of the SYNERGY stent system are described in **Table V-T1**.

(B)

(C)

Sources: FDA P150003 PMA, 2015

Claim 1

the **first** and **second phases** (D) being immiscible,

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System labeling.

V. DEVICE DESCRIPTION

The SYNERGY™ Everolimus-Eluting (SYNERGY) is a device/drug combinat for vascular lumen support (primary mc (everolimus) targeted towards reducing drug/polymer-coated balloon-expandable stent, pre-mounted on a Monorail™ (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The drug/polymer coating consists of a bioabsorbable polymer, poly (D,L-lactide-co-glycolide) (PLGA), and the active pharmaceutical ingredient, everolimus. The characteristics of the SYNERGY stent system are described in **Table V-T1**.

(D)

Drug Product	An abluminal (outer surface of the stent) coating of a polymer carrier with approximately 1 µg of everolimus per mm^2 of total stent surface area with a maximum nominal drug content of 287.2 µg on the largest stent (4.00 x 38 mm).

Table V-T1: SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System Product Description

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Available Stent Diameters (mm)	2.25, 2.50, 2.75, 3.00, 3.50, 4.00	
Stent Material	Platinum Chromium Alloy (PtCr)	
Stent Strut Thickness	0.074 mm for diameters 2.25 mm to 2.75 mm 0.079 mm for diameters 3.00mm to 3.50 mm 0.081 mm for diameter of 4.00 mm	
Drug Product	An abluminal (outer surface of the stent) coating of a polymer carrier with approximately 1 µg of everolimus per mm^2 of total stent surface area with a maximum nominal drug content of 287.2 µg on the largest stent (4.00 x 38 mm).	
Delivery System		
Effective Length	144 cm	
Delivery System Y-Adapter Ports	Single access port to inflation lumen. Guidewire exit port is located approximately 25 cm from tip. Designed for guidewire ≤0.014 inches (0.36 mm)	Y-Connector (Side arm for access to balloon inflation/deflation lumen. Straight arm is continuous with shaft inner lumen). Designed for guidewire ≤0.014 inches (0.36 mm)
Stent Delivery	A balloon, with two radiopaque balloon markers, nominally placed 0.4 mm (0.016 inches) beyond the stent at each end.	
Balloon Inflation Pressure	Nominal Inflation Pressure: • Diameters 2.25 mm, 2.50 mm, 2.75 mm, 3.00 mm, 3.50 mm, 4.00 mm: 11 atm (1117 kPa)	
	Rated Burst Inflation Pressure: • Diameters 2.25 mm – 2.75 mm: 18 atm (1827 kPa) • Diameters 3.00 mm – 4.00 mm: 16 atm (1620 kPa)	

PMA P150003: FDA Summary of Safety and Effectiveness Data Page 2

Sources: FDA P150003 PMA, 2015

Claim 1

and wherein the **second phase** comprises **(E) one or more therapeutic agents**.

IV. **WARNINGS AND PRECAUTIONS**

The warnings and precautions can be found in the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System labeling.

V. **DEVICE DESCRIPTION**

The SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY) is a device/drug combination product that provides a mechanical structure for vascular lumen support (primary mode of action) and a pharmacological agent (everolimus) targeted towards reducing the injury response. The System consists of a drug/polymer-coated balloon-expandable stent, pre-mounted on a Monorail™ (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The drug/polymer coating consists of a bioabsorbable polymer, poly (D,L-lactide-co-glycolide) (PLGA), and the active pharmaceutical ingredient, everolimus. The characteristics of the SYNERGY stent system are described in **Table V-T1**.

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Delivery System		
Effective Length	144 cm	
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Balloon Inflation Pressure	Nominal Inflation Pressure: • Diameters 2.25 mm, 2.50 mm, 2.75 mm, 3.00 mm, 3.50 mm, 4.00 mm: 11 atm (1117 kPa)	
	Rated Burst Inflation Pressure: • Diameters 2.25 mm – 2.75 mm: 18 atm (1827 kPa) • Diameters 3.00 mm – 4.00 mm: 16 atm (1620 kPa)	

PMA P150003: FDA Summary of Safety and Effectiveness Data Page 2

DEVICE DESCRIPTION

The SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY) is a device/drug combination product that provides a mechanical structure for vascular lumen support (primary mode of action) and a pharmacological agent (everolimus) targeted towards reducing the injury response. The System consists of a drug/polymer-coated balloon-expandable stent, pre-mounted on a Monorail™ (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The drug/polymer coating consists of a bioabsorbable polymer, poly (D,L-lactide-co-glycolide) (PLGA), and the active pharmaceutical ingredient, everolimus. The characteristics of the SYNERGY stent system are described in **Table V-T1**.

(E)

Sources: FDA P150003 PMA, 2015